

EXHIBIT 4



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/467,271	05/16/2009	Ashok Wahi	51900-TRUTEK-009	7676
34325	7590	08/25/2011		
STANLEY H. KREMEN 4 LENAPE LANE EAST BRUNSWICK, NJ 08816			EXAMINER HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER
			1629	
			NOTIFICATION DATE	DELIVERY MODE
			08/25/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@patentsgroup.com

Office Action Summary**Application No.**

12/467,271

Applicant(s)

WAHI, ASHOK

Examiner

RAYMOND HENLEY III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/16/2009 and papers subsequent thereto.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-23 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-23 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/16/2009</u> . | 6) <input type="checkbox"/> Other: ____. |

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CLAIMS 1-23 ARE PRESENTED FOR EXAMINATION

Applicant's Information Disclosure Statement filed May 16, 2009 has been received and entered into the application. As reflected by the attached, completed copies of form PTO/SB/08, (3 sheets), the cited references have been considered.

Overcoming the Rejection Below

In order to overcome the rejection set forth *infra*, it is suggested that Applicant consider amending claims 1, 2 and 8 so as to delete the term "preventing" and replacing it with the term "inhibiting". While the latter is not specifically set forth in the present specification, it is nevertheless deemed that the concept thereof clearly finds support therein when the specification's teachings are taken as a whole, i.e., no new matter would be introduced by the introduction of the term "inhibition" in the claims.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for, at the most, inhibition of infections, does not reasonably provide enablement for the prevention of the same, (see claims 1, 2 and 8; and thus the claims dependent therefrom). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First Paragraph

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

“[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling.” (emphasis added).

Here, the objective truth of the statement that an infection, which is taken to mean the introduction of an infectious element through the outside of a given host and into the system of such host, (see MPEP § 2113; terms given their broadest reasonable interpretation), may be prevented, (which again, given its broadest, reasonable interpretation), i.e., a material is ever kept from introduction into the system of a host, is doubted because the present claims merely recite a pharmacological composition while an effective prevention against the introduction of an infectious material into a host, especially where such material does not cause any pathology, would require that the exterior system of the host to be completely blocked so as to preclude any infectious material passing through such system and arriving within the system of the host.

In reading the present specification as a whole, it appears the tenor thereof is that infections, whether they cause a pathology or not, may be **inhibited** rather than be prevented. The former allowing at least one infectious material to pass into the system of the host rather than the latter which indicates that not even one of the infectious material is allowed to infect, i.e., pass into the system of the host.

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As indicated above, the term “preventing” is here being interpreted as being synonymous with a circumstance such as where a vaccine is administered against a pathogen and the host to whom such was administered does not suffer from the pathogen’s effect even when present in the host’s system. As such the term “preventing” circumscribes a circumstance of almost absolute success. Because such success is not reasonably possible with the treatment of most infectious diseases/disorders, especially those having an etiology and pathophysiological manifestations as complex/poorly understood as encompassed by the present claims, the specification, which lacks an objective showing where prevention is actually manifest, is viewed as lacking an enabling disclosure of the same.

The Examiner notes that the term “prevent” is not *necessarily* synonymous with “cure” or the action of a vaccine, but such interpretation is proper given that “During patent examination, the pending claims must be ‘given their broadest reasonable interpretation consistent with the specification.’ *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969).” (MPEP § 2111).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAYMOND HENLEY III whose telephone number is (571)272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey S. Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Raymond J Henley III/
Primary Examiner
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August 19, 2011